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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/551,054 | 09/23/2005 | Martin F Bachmann | 1700.0590000/BJD/SJE | 1432 |

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| EXAMINER | |
|---|---|
| MOSHER, MARY | |
| ART UNIT | PAPER NUMBER |
| 1648 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/551,054 | BACHMANN ET AL. | |
| | Examiner | Art Unit | |
| | Mary E. Mosher, Ph.D. | 1648 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *04 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,7,9,11,12,14-16,18,21-24,26-28,30,32,38,46,89-94 and 97-103* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/14/08, 7/13/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,2,5,7,9,11,12,14-16,18,21-24,26-28,30,32,38,46,89-94 and 97-103.

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election without traverse of species (a), unmethylated CpG-containing oligonucleotides in the reply filed on 2/4/08 is acknowledged.

### *Claim Rejections - 35 USC § 112*

Claims 1, 2, 5, 7, 9, 11, 12, 14-16, 18, 21-24, 26-28, 30, 32, 38, 46, 89-94, 97-103 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 requires "a human melanoma MelanA peptide analogue." The specification defines this phrase as meaning "a peptide in which the amino acid sequence of the corresponding normal MelanA peptide is altered by at least one amino acid or amino acid derivative, wherein this alteration may comprise an amino acid substitution and/or deletion and/or insertion or a combination thereof." The specification further defines "normal MelanA peptide" as consisting of or comprising SEQ ID NO: 78 or 79. Is the term "MelanA analogue" meant to encompass every polypeptide which is not identical to SEQ ID NOs 78 or 79? If not, then the metes and bounds of the claim are indefinite. This affects dependent claims 2, 9, 11, 12, 14, 18, 21-24, 26-28, 30, 32, 38, 46, 89-94, 97-103.

In addition, claim 1 requires a substance "bound to said virus-like particle," which is clear on first glance. However, the specification defines this term more broadly than its conventional meaning, as also encompassing packaging without any actual covalent or noncovalent binding. Since the intended scope of the claim is confused by the

unconventional definition of the term, it is suggested that the claim be clarified by amendment to "bound to or packaged in said virus-like particle." This affects all of the dependent claims.

In claims 7, 15, 16, should “has an amino sequence” be read as “consists of the sequence,” “comprises the sequence,” or “comprises any part of the sequence” ? This affects the scope of the claims.

Claims 92-94, 97-103 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a useful immunogenic composition, does not reasonably provide enablement for a vaccine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification provides evidence that the virus-like particles presenting a MelanA peptide variant and a CpG oligonucleotide induce a useful immune response. However, the specification does not provide evidence that the immune response is effective to prevent human melanoma, as required by the use of the term "vaccine". Considering the state of the art, the teachings in the specification, and the absence of a working example of a disease-preventing vaccine, it is concluded that undue experimentation would be required to enable the full scope of the invention as claimed.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 5, 7-9, 11, 12, 14-16 18, 21-24, 26-28, 30, 32, 38, 46, 89-94, 97-103 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5, 7, 8, 10, 13-20, 34, 35, 100, 119-121, 126, 127, 138-145 of copending Application No. 10550518. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass the same CpG oligonucleotide packaged in a MelanA-virus-like particle. See particularly copending claims 14, 126, and 127.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 2, 5, 7-9, 11, 12, 14-16 18, 21-24, 26-28, 30, 32, 38, 46, 89-94, 97-103 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 8-53, 56-77, 79-128, 132-154, 184-207 of copending Application No. 10244065. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims

encompass the same CpG oligonucleotide bound to or packaged in a MelanA-virus-like particle. See particularly copending claims 5(i) and 59.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 2, 5, 7-9, 11, 12, 14-16 18, 21-24, 26-28, 30, 32, 38, 46, 89-94, 97-103 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 10, 14-16, 33, 34, 41, 48, 50, 55, 57, 63, 64 of copending Application No. 10563944. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass the same CpG oligonucleotide bound to or packaged in a MelanA-virus-like particle. See particularly claim 23(j) of this application and claim 50 of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 2, 5, 7-9, 11, 12, 14-16 18, 21-24, 26-28, 30, 32, 38, 46, 89-94, 97-103 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10, 12, 14-19, 23 of copending Application No. 11663350. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass the same CpG oligonucleotide bound to or packaged in a MelanA-virus-like particle. See particularly claim 21(j) of the current application and claims 9(bb), 14, and 15 of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 9, 11, 12, 14, 18, 21-24, 26-28, 30, 32, 38, 46, 89-94, 97-103 are rejected under 35 U.S.C. 102(e) as being anticipated by US2003/0099668. See the abstract and paragraph 0332 for example. Any of the peptides which are not identical to SEQ 78 or 79 constitute a “MelanA analogue” as broadly defined.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5, 7, 8, 15, 16 are rejected under 35 U.S.C. 103(a) as being obvious over US2003/0099668 in view of Blanchet et al (Journal of Immunology 167:5858-5861, 2001. US2003/0099668 teaches superior immune responses to antigen-presenting virus-like particles which are loaded with CpG oligonucleotides. The reference differs from these claims in that it teaches use of a wild-type MelanA peptide in paragraph 0332. However, Blanchet teaches that an analogue with two substitutions, (ELAGIGLTV), provides superior response. Therefore it would have been obvious to substitute the analogue sequence for the sequence taught in the primary reference, for the purpose of obtaining the superior response taught in the secondary reference. The invention as a whole is prima facie obvious, absent unexpected results.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention “by another”; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the

application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The following references are cited as illustrating the state of the art:

Miconnet et al, "CpG are efficient adjuvants for specific CTL induction against tumor antigen-derived peptide," Journal of Immunology (2002), 168(3), 1212-1218.

Romero et al, "Antigenicity and immunogenicity of Melan-A/MART-1 derived peptides as targets for tumor reactive CTL in human melanoma," Immunological reviews, Oct 2002, 188, 81-96.

Le Gal et al, "Lipopeptide-based melanoma cancer vaccine induced a strong MART-27-35-cytotoxic T lymphocyte response in a preclincal study," International journal of cancer, Mar 10 2002, 98(2), 221-227.

Storni et al, "Critical role for activation of antigen-presenting cells in priming of cytotoxic T cell responses after vaccination with virus-like particles," Journal of immunology, Mar 15 2002, 168(6), 2880-2886 (in IDS)

Clark et al, "Immunity against both polyoma virus VP1 and a transgene product induced following intranasal delivery of VP1 pseudocapsid-DNA complexes," J.Gen.Virol. (82, Pt.11, 2791-97) 2001 (in IDS).

Shi et al, "Papillomavirus pseudovirus: a novel vaccine to induce mucosal and systemic cytotoxic T-lymphocyte responses," Journal of virology, Nov 2001, 75(21), 10139-10148.

## *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on varying dates and times; please leave a message.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher, Ph.D./
Primary Examiner, Art Unit 1648

4/8/08